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09/943,215	08/30/2001	Sheng-Zhi Pang	19603/1559 (CRF D-2052C)	9965

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,215

Applicant(s)

PANG ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 93-121 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 93-121 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on with the application is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 1/2.
- 4) Interview Summary (PTO-413) Paper No(s) g.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

1. Claims 93-121 are pending.
2. The draftsman has approved the drawings as submitted.
3. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.
4. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

5. Claims 94, 96-101, 103-109, and 111- 121 are objected to because of the following informalities:

Claims 94, 97, 99, 101, 103-109, 112, 114-115, 117, 119 and 121 start with an improper article.

Claims 96, 98, 100, 111, 113, 116, 118 and 120 have an improper article before "DNA".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 93-121 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of DNA constructs that comprise a fusion gene comprising one or more trait DNAs, wherein one trait DNA encodes papaya ringspot viral coat protein, or that comprise a fusion gene comprising a silencer and a trait DNA encoding papaya ringspot viral coat protein, methods of using those constructs, and plants and plant seeds comprising those constructs. In contrast, the specification only describes a trait DNA molecule from the tomato spotted wilt virus and silencer DNA molecules that are the green fluorescent protein and the turnip mosaic potyvirus coat protein genes. Applicant does not describe other DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided. No description is provided as to structural features (*i.e.*, sequences) that distinguish trait and silencer DNAs from other nucleic acids or from each other. Furthermore, Applicant does not describe plants having all of the myriad of potential traits as broadly claimed.

Hence, Applicant has not, in fact, described DNA constructs that comprise a fusion gene comprising one or more trait DNAs, wherein one trait DNA encodes papaya ringspot viral coat protein, or that comprise a fusion gene comprising a silencer and a trait DNA encoding papaya ringspot viral coat protein within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention

and at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

8. Claims 93-121 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to DNA constructs that comprise a fusion gene comprising one or more trait DNAs with a length insufficient to impart the trait, wherein one trait DNA encodes papaya ringspot viral coat protein, or that comprise a fusion gene comprising a silencer and a trait DNA encoding papaya ringspot viral coat protein, wherein the trait DNA has a length

insufficient to impart the trait, methods of using those constructs, and plants and plant seeds comprising those constructs.

The instant specification, however, only provides guidance for plant expression vectors comprising portions of the N gene of the lettuce isolate of the tomato spotted wilt virus alone or fused to the green fluorescent protein open reading frame and plants transformed with those constructs (example 1), ELISA and Northern blot analysis of the transgenic plants (examples 2 and 5-6), inoculation of the transgenic plants with tomato spotted wilt virus (examples 3 and 5-6), nuclear run-off transcription assays of the transgenic plant nuclei (examples 4-6), and DNA constructs comprising portions of the N gene of the lettuce isolate of the tomato spotted wilt virus fused to the turnip mosaic potyvirus coat protein gene, transformation into plants, and inoculation of the transgenic plants with multiple viruses to demonstrate the plants are resistant to turnip mosaic potyvirus and tomato spotted wilt virus (example 7).

The instant specification fails to provide guidance for constructs wherein the trait DNA encodes papaya ringspot viral coat protein, methods of using those constructs, and plants and plant seeds comprising those constructs.

The instant specification also fails to provide guidance for the minimum sizes of the trait and silencer DNA molecules. The specification fails to provide guidance for silencers that are combinations of viral DNA molecules, fluorescent protein encoding DNA molecules, plant DNA molecules and or viral gene silencers.

Jan et al (2000, J. Gen. Virol. 81:235-242) teach that the minimum length of the N gene trait DNA in such a gene-silencing construct was 110 nucleotides (pg 239, paragraph spanning

Art Unit: 1638

the columns). The instant specification fails to teach this limitation. The instant specification also fails to teach the minimum length of other trait DNAs.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 93-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 93 is indefinite in their use of the term "trait DNA". It is unclear what a trait DNA is. It is unclear what DNAs are encompassed by the phrase. Does it encode something?

Claims 102, 104-106, 109 and 114 are indefinite in their use of the term "silencer DNA". It is unclear what DNAs are encompassed by the phrase. As the silencer DNA can encode a protein (*e.g.*, pg 19, lines 4-16), it would also appear to be a "trait DNA". It is unclear what this silencer DNA is - does it encode something? Is it a promoter? What does it silence?

Claim 102 is indefinite in its recitation of "operatively coupled". The operation for which the DNA is coupled is unclear - is it coupling for purposes of transformation? For silencing? It is also unclear what manner of coupling is considered operative.

Claims 93 and 102 are indefinite in their recitation of "fusion gene". It is unclear if the phrase is intended to simply mean both the silencer and trait DNAs are on the same construct or if they are intended to interact with one another or what. Additionally, as a gene already

comprises a promoter and a termination sequence, it is unclear where the promoters and termination sequences of claims 94 and 103 are located on the DNA constructs.

Claims 96 and 111 are indefinite in their recitation of "a host cell transduced" as transduction is viral-mediated genetic transfer between bacteria. Thus, the host cell cannot be a virus, a yeast cell or a plant cell, as specified in dependent claims 97 and 112. Additionally, a virus is not a cell.

Claim 102 is indefinite in its recitation of "effective to achieve post-transcriptional silencing" in line 5-6 and claim 107 is indefinite in its recitation of "effects post-transcriptional silencing". It is unclear what is being post-transcriptionally silenced.

Claim 104 is indefinite in its recitation of "plant DNA molecule". It is unclear if this DNA molecule is from a plant or is one that can be put into a plant.

It is unclear how the trait DNA, in claim 106, can be nontranslatable when parent claim specifies that the trait DNA encodes a papaya ringspot viral coat protein.

Claim 108 lacks antecedent basis for the limitations "the trait DNA" and the "silencer DNA molecules" and claim 102 refers to a trait DNA molecule and a silencer DNA molecule.

Claims 118-121 are indefinite because they lack agreement between the preamble of the methods and the positive method steps. Methods must be circular; the final step must generate the item the method is intended to produce. For example, the method of imparting a trait to plants in claim 118 ends in transforming a plant with a DNA construct, when it should end in the production of a plant that has the trait.

It is unclear how in the methods of claims 118-121, one can impart a trait to plants by transforming a single plant. Either "plants" should be replaced with --a plant-- or additional steps that generate plants from a plant should be added.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 93-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tricoli et al (WO 96/21031).

The claims are drawn to DNA constructs that comprise a fusion gene comprising one or more trait DNAs with a length insufficient to impart the trait, wherein one trait DNA encodes papaya ringspot viral coat protein, or that comprise a fusion gene comprising a silencer and a trait DNA encoding papaya ringspot viral coat protein, wherein the trait DNA has a length insufficient to impart the trait, methods of using those constructs to impart a trait to plants and plants and plant seeds comprising those constructs.

Tricoli et al teach a DNA construct, pPRCPW, that comprises the "trait DNA" of the amino terminal portion of the cucumber mosaic virus (CMV) coat protein ORF and a silencer DNA, the watermelon mosaic virus-2 (WMV-2) coat protein ORF (pg 22, lines 15-28). The trait gene is insufficient to impart the trait but the silencer and trait DNAs together can impart the trait. Additionally, the silencer DNA can be considered a trait DNA, so the construct would

Art Unit: 1638

comprise a plurality of different trait DNAs, at least one of which is insufficient to impart the trait and at least one is long enough to impart the trait. A CaMV 35S promoter drives transcription and the construct comprises a termination signal.

Tricoli et al also teach DNA constructs comprising multiple trait DNA molecules on the DNA construct, wherein one of the trait DNAs is papaya ringspot virus ORF (pg 25-26). The ORFs would encode RNAs that are translatable.

Tricoli et al also teach squash, cantaloupe, cucumber and watermelon plants transformed with expression vectors comprising these constructs, and R₁ and R₂ seeds and plants produced from the transgenic plants (pg 26-39).

Tricoli et al do not disclose constructs comparing a trait DNA molecule and a silencer DNA molecule, wherein the trait DNA from papaya ringspot virus.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the construct taught by Tricoli et al, to make the trait DNA the papaya ringspot virus coat protein gene. One of ordinary skill in the art would have been motivated to do so because of the success Tricoli had in obtaining plants with resistance to multiple viruses (pg 26-39), and because the exact combination of viral resistance sequences used in a particular construct is an obvious design choice. Tricoli et al also suggest using DNAs that encode RNAs that are non-translatable (pg 19, lines 12-17).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1638

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 93- are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 12 and 36 of copending Application No. 09/025,635. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because DNA constructs that comprise a fusion gene comprising one or more trait DNAs with a length insufficient to impart the trait, wherein one trait DNA encodes papaya ringspot viral coat protein, or that comprise a fusion gene comprising a silencer and a trait DNA encoding papaya ringspot viral coat protein, wherein the trait DNA has a length insufficient to impart the trait, as claimed in the instant application, is obvious over DNA constructs that comprise a trait DNA that has a length insufficient to impart the trait a comprises a silencer DNA, wherein the trait DNA and the silencer DNA are transcribed from the same promoter and wherein the trait DNA encodes papaya ringspot viral coat protein, as claimed in the copending

Art Unit: 1638

application, because in the DNA constructs of the copending application the trait and silencer DNAs must be organized into a fusion gene. Additionally, in the DNA constructs that comprise a fusion gene comprising one or more trait DNAs with a length insufficient to impart the trait, wherein one trait DNA encodes papaya ringspot viral coat protein, as claimed in the instant application, one of the trait DNAs acts as a silencer DNA.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
January 8, 2003



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